

Jul 13 Rec'd PCT/PTO 02 JAN 2002

PTO/SB/08A (08-00)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2

Application Number 09/875,456
Filing Date June 6, 2000
First Named Inventor Qin, et al.
Group Art Unit 1615
Examiner Name
Attorney Docket Number ORT-1448

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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			T ²
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	
2		BALSER, JEFFREY R. STRUCTURE AND FUNCTION OF THE CARDIAC SODIUM CHANNELS. Cardiovascular Research (1999) 42:327-338	/
2		Catterall, William A., CELLULAR AND MOLECULAR BIOLOGY OF VOLTAGE-GATED SODIUM CHANNELS. Pharmaceutical Rev., Vol. 22, No. 4 (1991) William A. STRUCTURE AND FUNCTION OF VOLTAGE-GATED ION CHANNELS, Trends Neurosci 16:5-506 (1993)	/
2		Chabal, Charles, et al., THE EFFECT OF INTRAVENOUS LIDOCAINE, TOCAINIDE, AND MEXILETINE ON SPONTANEOUSLY ACTIVE FIBERS ORIGINATING IN RAT SCIATIC NEUROMAS, Pain, 38 (199) 333-338	/
2		Chaplan, S.R., et al., QUANTITATIVE ASSESSMENT OF TACTILE ALLODYNIA IN THE RAT PAW, Journal of Neuroscience Methods 53 (1994) 55-63	/
2		D'Andrea, Michael R., et al. CHARACTERIZATION OF PROTEASE-ACTIVATED RECEPTOR-2 IMMUNOREACTIVITY IN NORMAL HUMAN TISSUES, Journal of Histochemistry & Cytochemistry, Vol. 46(2): 157-164 (1998)	/
2		Devor, Marshall et al., NA ⁺ CHANNEL ACCUMULATION ON AXOLEMMA OF AFFERENT ENDINGS IN NERVE END NEUROMAS IN APTERONOTUS, Neuroscience Letters, 102 (1989) 149-154	/
2		Devor, Marshall, THE PATHOPHYSIOLOGY OF DAMAGED PERIPHERAL NERVES, In Textbook of Pain, eds. 79-101 (1994)	/
2		Devor, Marshall, et al. SYSTEMIC LIDOCAINE SILENCES ECTOPIC NEUROMA AND DRG DISCHARGE WITHOUT BLOCKING NERVE CONDUCTION, Pain, 48 (1992) 261-268	/
2		Dib-haji, et al. Down-Regulation of Transcripts for Na Channel α -SNS IN SPINAL SENSORY NEURONS FOLLOWING AXOTOMY, Neurobiology (1998) Vol. 93, 14950-14954.	/
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2		England JD, Gamboni F, Ferguson MA, Levinson SR (1994) Sodium channels accumulate at the tips of injured axons. Muscle Nerve 17:593-598.	/
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2		Isom, L.L., et al. PRIMARY STRUCTURE AND FUNCTIONAL EXPRESSION OF THE β_1 SUBUNIT OF THE RAT BRAIN SODIUM CHANNEL, Science (1992), Vol. 356.	/
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2		ISOM, L.L., et al. AUXILIARY SUBUNITS OF VOLTAGE-GATED ION CHANNELS, Neuron, (1994), Vol 12 1183-1194	/
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2		Matzner O, Devor M (1994) Hyperexcitability at sites of nerve injury depends on voltage-sensitive Na ⁺ channels. J Neurophysiol 72:349-359.	/

Examiner Signature	Date Considered
<i>[Signature]</i>	3-11-00

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Application Number	09/875,456
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Sheet 2 of 2

Application Number	09/875,456
Filing Date	June 6, 2001
First Named Inventor	Qin, et al.
Group Art Unit	1615
Examiner Name	
Attorney Docket Number	ORT-1448

2	MCDONNELL, D. et al. RECONSTRUCTION OF THE VITAMIN D-RESPONSIVE OSTEOCALCIN TRANSCRIPTION UNIT IN SACCHAROMYCES CEREVISIAE, <i>Molecular & Cellular Biology</i> , (1989) Vol.9 No. 8: 3517-3523	✓
2	NORDIN, et al., ECTOPIC SENSORY DISCHARGES AND PARESTHESIAE IN PATIENTS WITH DISORDERS OF PERIPHERAL NERVES, DORSAL ROOTS AND DORSAL COLUMNS, <i>Pain</i> 20 (1984), 231-245	✓
2	OCHOA, et al., PARAESTHESIAE FROM ECTOPIC IMPULSE GENERATION IN HUMAN SENSORY NERVES, <i>Brain</i> (1980) 103, 835-853	✓
2	Oh, Youngsuk, et al., Na ⁺ Channel β 1 SUBUNIT mRNA; DIFFERENTIAL EXPRESSION IN RAT SPINAL SENSORY NEURONS, <i>Molecular Brain Research</i> , (1995) 357-361	✓
2	Omana-Zapata, Imelda, et al., TETRODOTOXIN INHIBITS NEUROPATHIC ECTOPIC ACTIVITY IN NEUROMAS, DORSAL ROOT GANGLIA AND DORSAL HORN NEURONS, <i>Pain</i> 72 (1997) 41-49	✓
2	Porreca, Frank, et al., A COMPARISON OF THE POTENTIAL ROLE OF THE TETRODOTOXIN-INSENSITIVE SODIUM CHANNELS, PN3/SNS AND NAN/SNS2, IN RAT MODELS OF CHRONIC PAIN, <i>Proc. Natl. Acad. Sci., USA</i> , Vol. 96 (1999) 7640-7644	✓
2	Riehl-Bellon, Nadine et al., PURIFICATION AND BIOCHEMICAL CHARACTERIZATION OF RECOMBINANT HIRUDIN PRODUCED BY SACCHAROMYCES CEREVISIAE, <i>Biochemistry</i> (1989) 2941-2949	✓
2	Rinas, Ursula, et al., CHARACTERIZATION OF RECOMBINANT FACTOR XIIIa PRODUCED IN SACCHAROMYCES CEREVISIAE, <i>Biotechnology</i> (1990), 543-546	✓
2	Rizzo, Marco A., SUCCESSFUL TREATMENT OF PAINFUL TRAUMATIC MONONEUROPATHY WITH CARBAMAZEPINE; INSIGHTS INTO A POSSIBLE MOLECULAR PAIN MECHANISM, <i>Journal of Neurological Sciences</i> , (1997) 103-106	✓
2	SABIN, E. et al., HIGH-LEVEL EXPRESSION AND IN VIVO PROCESSING OF CHIMERIC UBIQUITIN FUSION PROTEINS IN SACCHAROMYCES CEREVISIAE, <i>Biotechnology</i> (1989) Vol. 7: 705-709	✓
2	Sleep, D. et al., THE SECRETION OF HUMAN SERUM ALBUMIN FROM THE YEAST SACCHAROMYCES CEREVISIAE USING FIVE DIFFERENT LEADER SEQUENCES, <i>Biotechnology</i> , Vol., 8 (1990) 42-45	✓
2	Sutkowski et al., β 1 SUBUNITS OF SODIUM CHANNELS, <i>The Journal of Biological Chemistry</i> (1990) 12393-12399	✓
2	Tanaka, M., et al., SNS NA ⁺ CHANNEL EXPRESSION INCREASES IN DORSAL ROOT GANGLION NEURONS IN THE CARRAGEENAN INFLAMMATORY PAIN MODEL, <i>Molecular Neuroscience</i> , vol. 9 (1998) 967-972	✓
2	Wallace, R. H., et al., FEBRILE SEIZURES AND GENERALIZED EPILEPSY ASSOCIATED WITH A MUTATION IN THE NA ⁺ -CHANNEL β 1 SUBUNIT GENE SCN1B, <i>Nature America Inc.</i> (1998), 366-370	✓
2	Waxman, Stephen, et al., CONDUCTIN THROUGH DEMYELINATED PLAQUES IN MULTIPLE SCLEROSIS; COMPUTER SIMULATIONS OF FACILITATION BY SHORT INTERNODES, <i>Journal of Neurology, Neurosurgery, and Psychiatry</i> (1978) 408-416	✓
2	Waxman, S.G., et al., SODIUM CHANNELS AND PAIN, <i>Proc. Natl. Acad. Sci, USA</i> , 1999 Vol 96 7635-7639	✓
2	WAXMAN SG, ET AL. (1994) TYPE III SODIUM CHANNEL MRNA IS EXPRESSED IN EMBRYONIC BUT NOT ADULT SPINAL SENSORY NEURONS, AND IS REEXPRESSED FOLLOWING AXOTOMY. <i>J NEUROPHYSIOL</i> 72:466-470.	✓
2	Woolf CJ, et al., (1994) Nerve growth factor contributes to the generation of inflammatory sensory hypersensitivity. <i>Neuroscience</i> 62:327-331.	✓
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For the

1-31-03

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Qin et al.

Serial No. : 09/875,456

Art Unit: 1653

Filed : June 6, 2001

Examiner:

For :

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(Name of applicant, assignee, or Registered Representative)

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December 31, 2001

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Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37
C.F.R. §§1.97-1.98, information relating to the above-identified
application is hereby disclosed. Inclusion of information in
this statement is not to be construed as an admission that this
information is material as that term is defined in 37 C.F.R.
§1.56(b).

Applicant(s) reserve(s) the right to establish the
patentability of the claimed invention over any of the
information provided herewith, and/or to prove that this
information may not be prior art, and/or to prove that this

information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Statement in Accordance with §1.97(e) (attached);
or

☐ Please charge Deposit Account No. 10-0750/ /
the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached);
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☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☒ There are no listed references which are not in the English language.

☐ The relevance of those listed references which are not in the English language is as follows:

☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☒ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/ORT-1448/MHM. This form is submitted in triplicate.

Respectfully submitted,

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DATED: December 31, 2001